ETHICS COMMITTEE - SVDCH

STANDARD OPERATING PROCEDURES

2020

VERSION 1.0

Prepared and reviewed by the Secretariat of the Ethics Committee, Sri Venkateswara Dental College and Hospital, Thalambur, Chennai

STANDARD OPERATING PROCEDURES

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1. INTRODUCTION

Sri Venkateswara Dental College & Hospital (SVDCH), a unit of Vels Deemed University, affiliated to the Tamil Nadu Dr MGR Medical University, is a renowned institution based at Thalambur, Chennai. The institution is marching past its 10th year since formation in 2007. SVDCH is one of the best institutions in the country in regard to academic activities, infrastructure, quality faculty, and all-round development of the individual. With a sprawling 8-acre campus, 250,000 sq ft of infrastructure and facilities for training 500 students every year, the hospital caters to the needs of more than 50,000 patients annually. The faculty team boasts the most eminent names in Indian dental academia. This has translated to stupendous student and faculty achievements over the past years. NAAC has accredited the institution in 2015.

The institution has an established institutional ethics committee, to review proposals of all research in which members of the institution (staff & students) are involved. This document has been prepared to provide information on & streamline the process of obtaining ethics approval for research projects.

Development of this procedural manual has been guided primarily by the recommendations made by the Indian Council of Medical Research (ICMR) in its guidelines for preparing standard operating procedures (SOP) for human research.

2. OBJECTIVES

This document has been developed for students and faculty involved in health-related research with human participants, including biomedical, behavioral, social science, and epidemiological research (throughout this document, the term "research" is meant to include, and refers to, all of these domains). In particular, this document is intended to provide guidance to the ethics committee (EC-SVDCH) to review and oversee the ethical aspects of research, as well as to the researchers who design and carry out oral health research. Therefore a Standard Operating Procedure (SOP) has been formulated.

This SOP facilitates the use of the institutional review process for those interested in research activities. The Ethics Committee - Sri Venkateswara Dental College & Hospital (EC-SVDCH) will conduct a central review process based on the ethical guidelines for biomedical research on human subjects by the Indian council of medical research(ICMR). This document shall put in place a consistent ethical review mechanism for oral health& biomedical research for all research proposals received by the committee. It will thus ensure that quality & consistency of an ethical review mechanism is scrupulously adhered.

3. FUNCTIONS AND DUTIES OF THE COMMITTEE

- To provide independent, competent, and timely review of the ethics of proposed studies.
- To contribute to safeguarding the dignity, rights, safety, and well being of all actual or potential research participants.
- To take into consideration the principle of justice-which requires that the benefits and burdens of research be distributed fairly among all groups and classes in society, taking into account age, gender, economic status, culture, and ethnic consideration
- EC will be independent from political, institutional, professional, and market influences
- To ensure that there is regular evaluation of the ethics of on-going studies that received a positive decision
- The EC will have due regard for the requirements of relevant regulatory agencies and applicable laws

4. COMPOSITION

4.1 MEMBERSHIP REQUIREMENTS AND TERMS OF APPOINTMENT:

- This EC is multidisciplinary and multi-sectorial in composition, and includes individuals with relevant scientific expertise, balanced age and gender distribution, and laypersons representing the interests and the concerns of the community.
- This EC has been constituted by direct invitation and appointment of members by the office of the Principal, Sri Venkateswara Dental College & Hospital, Chennai.
- At least 50% of members are not to be affiliated to the institution.
- Membership shall have balanced representation from medical and non-medical fields
- There has been no conflict of interest in making these appointments.
- The tenure of this EC is three years.
- The appointments will be renewed at the end of three years by consensus.
- There must be 7 to 15 members and a quorum of 5 members is essential for committee meetings.

Composition requirements

Member	Qualification	Description/Responsibility
Chairperson	Non-affiliated A well-respected person from any background with prior experience of having served/serving in an EC	To conduct meetings and ensure independence and proper functioning of the committee Ensure participation of members in meetings Ratify minutes of meetings In case of absence, shall nominate another member to act as Chair, with all powers and functions therein. Seek COI declaration from members, ensure no conflicts.

		Ensure quorum Handle conflicts, complaints, requests for information
Member Secretary	**Affiliated staff of institution** Should have knowledge and experience in clinical research and ethics, be motivated and have good communication skills Should be able to devote adequate time to this activity which should be protected by the institution	Organize an effective and efficient procedure for receiving, preparing, circulating and maintaining each proposal for review • Schedule EC meetings, prepare the agenda and minutes • Organize EC documentation, communication and archiving • Ensure training of EC secretariat and EC members • Ensure SOPs are updated as and when required • Ensure adherence of EC functioning to the SOPs • Prepare for and respond to audits and inspections • Ensure completeness of documentation at the time of receipt and timely inclusion in agenda for EC review. • Assess the need for expedited review/ exemption from review or full review. Assess the need to obtain prior scientific review, invite independent consultant, patient or community representatives. • Ensure quorum during the meeting and record discussions and decisions.
Basic Medical Scientist(s)	Affiliated/ non-affiliated	• Scientific and ethical review with special emphasis on the intervention, benefit-risk

	Qualifications - Non-medical or medical Person with qualifications in basic medical sciences In case of EC reviewing clinical trials with drugs, the basic medical scientist should preferably be a pharmacologist	analysis, research design, methodology and statistics, continuing review process, SAE, protocol deviation, progress and completion report • For clinical trials, pharmacologist to review the drug safety and pharmacodynamics.
Clinician(s)	**Affiliated/ non-affiliated** Should be individual/s with recognized medical qualification, expertise and training	Scientific review of protocols including review of the intervention, benefit-risk analysis, research design, methodology, sample size, site of study and statistics Ongoing review of the protocol (SAE, protocol deviation or violation, progress and completion report) Review medical care, facility and appropriateness of the principal investigator, provision for medical car, management and compensation. Thorough review of protocol, investigators brochure (if applicable) and all other protocol details and submitted documents.
Legal expert/s	**Non-affiliated**	Ethical review of the proposal, ICD along with

	Basic degree in Law from a recognized university, with experience • Desirable: Training in medical law.	translations, MoU, Clinical Trial Agreement (CTA), regulatory approval, insurance document, other site approvals, researcher's undertaking, protocol specific other permissions, compliance with guidelines etc. Interpret and inform EC members about new regulations if any
Social scientist/ philosopher/ ethicist/theologian	**Non-affiliated** Should be an individual with social/behavioral science/ philosophy/ religious qualification and training and/or expertise and be sensitive to local cultural and moral values. Can be from an NGO involved in health-related activities	Ethical review of the proposal, ICD along with the translations. Assess impact on community involvement, socio–cultural context, religious or philosophical context, if any. Serve as a patient/participant/ societal / community representative and bring in ethical and societal concerns.
Lay person(s)	**Non-affiliated** • Literate person from the public or community • Has not pursued a medical science/ health related career in the	Ethical review of the proposal, ICD along with translation(s) Evaluate benefits and risks from the participant's perspective and opine whether benefits justify the risks.

	last 5 years • May be a representative of the community from which the participants are to be drawn • Is aware of the local language, cultural and moral values of the community • Desirable: involved in social and community welfare activities	• Serve as a patient/participant/ community representative and bring in ethical and societal concerns. • Assess on societal aspects if any.

4.2 Quorum

- A minimum of five members present in the meeting room.
- The quorum should include both medical, non medical or technical or/and non-technical members.
- Minimum one non-affiliated member should be part of the quorum.
- Preferably the lay person should be part of the quorum.
- The quorum for reviewing regulatory clinical trials should be in accordance with current CDSCO requirements.
- No decision is valid without fulfillment of the quorum.

4.3 Additional requirements

- The head of the institution should not be part of the EC but should act as an appellate authority to appoint the committee or to handle disputes.
- The Chairperson and Member Secretary could have dual roles in the ethics committee.

- The EC can also have a set of alternate members who can be invited as members with decision-making powers to meet the quorum requirements. These members have the same TORs as regular members and can attend meetings in the absence of regular members.
- The EC can maintain a panel of subject experts who are consulted for their subject expertise, but will not have decision making power/voting rights.
- The EC may invite subject experts as independent consultants or include a representative from a specific patient group as a member of the EC or special invitee with appropriate decision making power.
- A separate scientific committee should also review proposals before it is referred to EC. EC can raise scientific queries besides ethical ones as both good science and ethics are important to ensure quality of research and participant protection.

4.4 Training of members

- EC members have a need for initial and continued education regarding the science and Ethics of biomedical research.
- All EC members must be conversant with ICMR Guidelines for Research involving Human Subjects 2006, Schedule Y of Drugs and Cosmetics Act and ICH-GCP guidelines.
- EC members will receive introductory training material in EC SOPs and research bioethics and will be exposed to ongoing opportunities for enhancing their capacity for ethical review.
- A new member will be inducted 1 month prior to his/her appointment and will be requested to be an ‘Observer’ for the first board meeting. An introductory training will be imparted by the Member Secretary.
- The EC members will be encouraged to receive ongoing training by attending workshops at least once every year.
- The EC will conduct workshops from time to time to impart training to the EC members and Institutional faculty members.
- The training programs should be scheduled regularly.

4.5 Conflicts of Interest

Appointed Members of the EC-SVDCH are required to sign the Confidentiality / Conflict of Interest Agreement and Financial Disclosure at the start of their term.

A conflict of interest may be identified as either financial in nature (such as when an EC member holds an economic interest in the research) or non-financial in nature (such as when an EC member or consultant participates in the research or will be included as a co-author on a publication from the research), either of which could affect or appear to affect the design, conduct, oversight, or reporting of the research project.

The confidentiality agreement protects the privacy and confidentiality of all parties whose information may be disclosed to the EC in the course of its work.

All EC members shall disclose in writing to the EC all conflicts of interest for themselves and their spouses/domestic partners and dependent children.

Financial interests that require disclosure include but are not limited to:

 Ownership interest, stock options, or other economic interest related to the research, Board, scientific officer, or executive relationship related to the research, regardless of compensation for that position.

Non-financial interests that require disclosure include but are not limited to:

a. Participation in the research project as key personnel (PI, Co-PI, sub-investigator);

b. Co-Author on a publication of the research project's results;

c. Other relationships which may influence judgment of the EC member in reviewing the research project:

- Is a direct supervisor or trainee of the researcher(s)
- Is related to a researcher whose protocol is under consideration
- Has a prominent role in a directly competing research team or product
- Has a close personal relationship with a researcher or for other reasons feels unable to render a fair and unbiased review.
- A member cannot participate in the review and approval process for any project in which he or she is present as a PI, Co-PI or CI or has any other potential conflict of interest

EC members are prohibited from participating in the review of a research protocol or plan in which they have a conflict of interest, except to provide information requested by the EC.

4.6 Resignation, disqualification and replacement:

Resignation Procedure:

A member of EC committee may resign his / her membership by writing to the chairperson for the reason found fit by him / her. The chairperson, depending upon the reasons cited in the resignation will accept resignation and he / she may notify it to the members.

Disqualification Procedure:

Members, who remain absent for 3 consecutive meetings without prior notice and permission of the Chairperson, can be considered for disqualification.

Replacement Procedure:-

The member of the same category shall fill a casual vacancy in the EC by nomination and acceptance of EC.

5. TERMS OF REFERENCE

The purpose of the institutional ethics committee is to conduct a bi-annual review and approval of institutional studies. Initial decision / approvals given for the clinical trials which would be undertaken will be monitored from time to time and whenever required. All proposals shall be submitted as per the SOP. The committee will review & make recommendations on all types of research proposals with a view to safeguard the dignity, rights, safety & well-being of all actual & potential research participants. The goals of research, however important, should not be permitted to override the health & well –being of the research subjects. The committee will take utmost care to preserve all the cardinal principles of research ethics taking adequate care in planning, conduct & reporting of the proposed research as envisioned in the ICMR guidelines. For this purpose, the committee will screen the informed consent process, risk-benefit ratio, distribution of burden & provide necessary advice / support wherever required.

The committee will review the proposals prior to the start of the study & monitor the research throughout the study tenure, until & after completion of the study through appropriate, well-documented procedures, for e.g. regular reports, patient protocols etc.

The ultimate mandate of the committee will be to review all research projects involving human subjects / bio materials to be conducted at the institute, irrespective of the funding mechanism. In addition, each investigation shall be responsible to the committee, for proving the benefits of conducting trials on human subjects at risk. Utmost caution should be exercised

not to place the subjects at risk. All studies need to be approved before study procedures commence.

5.1 SCOPE OF ETHICAL REVIEW

- The relevance of the clinical trial and the trial design.
- Whether the evaluation of the anticipated benefits and risk is satisfactory and whether
- The conclusions are justified.
- The suitability of the Investigator and supporting staff.
- The quality of the facilities.
- The data available on the drug, procedure or device under study.
- The suitability of the protocol.
- The suitability of the patient information, consent forms and procedure.
- The arrangement for the recruitment of subjects.

EC may review different types of research studies, including, but not limited to, the following:

- CLINICAL TRIALS
- EPIDEMIOLOGICAL RESEARCH
- SOCIAL SCIENCE RESEARCH
- RESEARCH ON MEDICAL RECORDS OR OTHER PERSONAL INFORMATION
- RESEARCH ON STORED SAMPLES
- HEALTH SYSTEMS RESEARCH
- IMPLEMENTATION RESEARCH

EC will implement different methodologies and ethical considerations that apply to each type of proposed research they review.

5.2 ETHICAL BASIS FOR DECISION-MAKING IN ETHICS COMMITTEE

1. Scientific design and conduct of the study.
2. Selection of study population and recruitment of research participants.
3. Inducements, financial benefits, and financial costs.
4. Protection of research participants' privacy and confidentiality.
5. Risks and potential benefits.
6. Informed consent process.
7. Community consideration

Decisions on research protocols designated for review by the convened EC are based on a thorough and inclusive process of discussion and deliberation. Protocols involving no more than minimal risk and burden to research participants may be reviewed on an expedited basis by one or more members (rather than the full committee), if the REC has established written procedures permitting such a procedure.

During meetings of the EC, members engage in discussions to elicit all concerns and opinions related to the protocols and the associated documents under consideration. The EC rules ensure that the discussions are respectful of all opinions and allow for varied beliefs to be

aired. The Chair fosters a respectful and inclusive tone and allows adequate time for deliberation, during which only EC members participate and decisions are made only by those who were present during the entire discussion.

The Chair is responsible for the decision-making process, in particular for determining when consensus is needed to achieve the decision. Researchers, funders, or others directly associated with the protocol in question are not present during committee deliberations.

EC members recognize the limitations of their knowledge and seek how to develop the research proposal taking into account all the viewpoints.

6. PROCEDURE FOR SUBMISSION OF PROPOSALS

6.1 PROPOSAL REQUIREMENTS

The investigators are requested to develop their project proposals as per the pre-specified checklist. The proposal should be developed under the following titles:-

Introduction:

The proposal should have an "Introduction" section which states the need for the study under scrutiny. It should have a brief note on what is known (existing knowledge) about the given topic and what new will be added by doing the present study. It should also state as to how the present study will benefit the current state of practice / dental care / education etc. by accruing additional information.

A brief review of literature:

Literature review should be thorough, systematic and include well known facts and existing loopholes in the literature. It is more credible to review the recent literature from indexed journals. An attempt should be made to keep abreast of the global scenario as to what is happening at the international level, national level and regional level. It should also explore the strengths and limitations in the previously reported studies.

Objectives:

Aims & 'Objectives (Primary and Secondary) of the study should be clearly defined.

Material and Methods:

In the Methods section, the following should be clearly stated:

- The facility (Laboratory/hospital/community/college) where the present study will be implemented.

- The Department under which the proposed study is intended to be done.

Study design:

The type of study design to be implemented should be specified.

Study participants:

Whether Human / Animals / Laboratory samples / Secondary data etc are employed should be mentioned.

Sample size:

If quantitative research, sample size should be worked out on the basis of a „primary outcome" of the study and justified. It is better to avoid quoting feasible sample / convenient sample in quantitative research as it affects its external validity. In Qualitative research, the type of sample and sampling size should be worked out and described.

Sampling procedure:

Once the sample size has been decided, then the same should be selected from a suitable sampling frame by using some random selection methods, where every study participant has equal opportunity of participating in the study. Sampling procedures and the study period should be clearly defined. In case of clinical trials, the details regarding the individual Phase of the trial, randomization and blinding should be described.

Measurement:

Researchers are advised to develop a tool which is reliable and valid i.e. It measures what is expected accurately. Following standard questionnaire development practices is recommended. Please check copyright / permission / plagiarism issues if using a standard questionnaire. The details of study participants such as age, gender, etc. & their acceptability based on the inclusion criteria should be mentioned.

Ethical issues:

Mention should be made of the ethical issues you are expected to face and the strategy you are going to implement to minimize any potential harm. It is thus desirous to follow universally acclaimed Guidelines on Good Clinical Practice (GCP) while conducting clinical trials and CPCSEA (Committee for the Purpose of Control and Supervision of Experiments on Animals) guidelines in the conduct of animal experiments.

The consent forms for research on human subjects should have an informed consent form (in regional language) as per given template. It is also advised to follow Consolidated Criteria for Reporting Qualitative Research while conducting and reporting qualitative researches (Tong A, 2007). It is also highly recommended to anticipate ethical issues in the proposed research and make attempts to address these issues while designing the study itself.

Analysis:

The details of the study variables to be measured and the appropriate statistics and related instruments (tests of significance, levels etc. of significance) should be given. Analysis plan should be clearly worked out at the time of proposal development. Statistical software for the analysis of the proposed study data should be mentioned. Researchers are also advised to consult the research methodologist / biostatistician / epidemiologist during every phase of proposal development so as avoid discrepancies in the study.

6.2 SUBMITTING AN APPLICATION

The EC will review protocols involving studies to be conducted within the Dental College and Hospital. External protocols will also be accepted. The EC has established well-defined requirements for submitting an application for review of a research project. This includes a Protocol checklist and Plain language Summary (non technical language) that should accompany each protocol submitted for review. A qualified researcher responsible for the ethical and scientific conduct of the research should submit an application. Applications should be submitted to the Member Secretary at least 2 weeks prior to the proposed date of the meeting in 12 copies.

Incomplete applications will be returned to the investigator. In cases where the EC requests supplementary information or changes to documents from the applicant, the application will be reviewed in the next meeting. Investigators will be notified of the decision of the review within a period of 2 weeks.

- All proposals should be submitted in the prescribed application form, copies of which would be available with the Member Secretary.
- All relevant documents should be enclosed with application.
- The Head of the Department should forward the required number of copies of the proposal along with the application and documents in prescribed format duly signed by the PI and Co-investigators/Collaborators.
- The Member Secretary will acknowledge the receipt and indicate any lacunae. Missing information should be supplied within two weeks.

- The date of meeting will be intimated to the PI who should be available to offer clarifications if necessary.
- The decision of EC will be communicated in writing. If revision is to be made, the revised document in required number of copies should be submitted within a stipulated period as specified in the communication.

6.3 DOCUMENTS REQUIRED:

All research proposals should be submitted with the following:

- **Title** of the project, **Names** of the PI and Co-investigators with designation.
- Name of any other **Institute / Hospital / Field area** where research will be conducted.
- **Approval** of the Head of the Department.
- **Protocol** of the proposed research.
- **Ethical issues** in the study and plans to address these issues.
- **Annexures** like case report forms, questionnaires, follow–up cards, etc. to be used in the study.
- **Patient information sheet and informed consent form** in English / Hindi and local language(s) should be enclosed. The patient information sheet should provide adequate and complete information in understandable language. It should also assure that any new information that becomes relevant during the trial and is related to their participation would be given to them. The consent form should be as per schedule Y published in Gazette of India (2005).

- For any drug / device trial, all **relevant pre-clinical animal data and clinical trial data** from other centers within the country / other countries, if available.
- Any **regulatory clearances** required. Copy of clearances if obtained. This is necessary for any new drug / device not approved for marketing in India, justification for sending of biological samples outside India and use of radioactive pharmaceuticals in clinical studies.
- **Source of funding** and Budget along with the supporting documents.
- **Indemnity** issues including insurance for the compensation to the participants etc.
- An undertaking to immediately report **Serious Adverse Events** (SAE) to EC.
- Statement of **Conflicts of Interest**, if any.
- Plans for **Publication** of results–positive or negative–while maintaining the privacy and confidentiality of the study participants.
- Any other information relevant to the study.
- Agreement to submit **annual progress report and final report** at the end of study.
- The PI should provide the **details of other ongoing research projects** (Title of the project, Date of starting and duration, source and amount of funding).

7. REVIEW OF PROPOSALS

7.1 REVIEW MEETINGS

- Meetings will be held once in six months and more in case there are more than 5 proposals for review.
- EC members will be given 2 weeks time to read through the applications.
- Meetings will be minuted and these minutes approved at the subsequent meeting.
- The applicant, sponsor, and / or investigator may be invited to present the proposal or elaborate on specific issues.
- In case where an application under review has been submitted by a member of the EC, the member will not be permitted to take part in the decision making process.

7.2 TYPES OF REVIEW

7.2.1 FULL REVIEW - (if involving)

- Vulnerable population
- More than minimal risk
- Any other factor(s) that exclude expedited or exempt from review

7.2.2 EXPEDITED REVIEW (if involving)

- Minimal risk
- Minor deviation from approved research
- Continuing review after approval by full review

- Clinical materials in possession of institution
- Emergencies
- Approved drugs/medical devices in limited situations

7.2.3 EXCEMPT FROM REVIEW-

- Research on educational practices such as instructional strategies or effectiveness
- Comparison among instructional techniques, curricula, or classroom management methods.

7.2.4 REVIEW OF RESEARCH INVOLVING VULNERABLE POPULATIONS

Vulnerable persons are those who are relatively (or absolutely) incapable of protecting their own interests. More formally, they may have insufficient power, intelligence, education, resources, strength, or other needed attributes to protect their own interests. Effort may be made to ensure that individuals or communities invited for research be selected in such a way that the burdens and benefits of the research are equally distributed.

a. Research on genetics should not lead to racial inequalities;

b. Persons who are economically or socially disadvantaged should not be used to benefit those who are better off than them;

c. Rights and welfare of mentally challenged and mentally differently able persons who are incapable of giving informed consent or those with behavioral disorders must be protected. Appropriate proxy consent from the legal guardian should be taken after the person is well

informed about the study, need for participation, risks and benefits involved and the privacy and confidentiality procedures. The entire consent process should be properly documented;

d. Adequate justification is required for the involvement of participants such as prisoners, students, subordinates, employees, service personnel etc. who have reduced autonomy as research participants, since the consent provided may be under duress or various other compelling reasons.

e. Individuals whose willingness to volunteer in a research study may be unduly influenced by the expectation, whether justified or not, of benefits associated with participation, or of a retaliatory response from senior members of a hierarchy in case of refusal to participate may also be considered vulnerable.

Examples are members of a group with a hierarchical structure, such as medical, pharmacy, dental, and nursing students, subordinate hospital and laboratory personnel, employees of the pharmaceutical industry, members of the armed forces, and persons kept in detention.

<u>“Vulnerable" or "special" classes:</u>

(This list may not be exhaustive as there may be circumstances in which other groups are considered vulnerable, women for example, in an orthodox patriarchical society, or terminally ill cancer patients.)

- Pregnant women, human fetuses and neonates,
- Prisoners,
- Children,
- cognitively impaired persons

 STUDENTS and employees, sub-ordinates

 Minorities (as defined by national constitution and / or socio-economically backward, refugees and such others.

 Economically and/or educationally disadvantaged

 AIDS/HIV+ subjects.

 Terminally ill Subjects

 Geriatic population

Child participation

☐ Children will not be involved in research that can be carried out equally well with adults.

☐ The purpose of the research is to obtain knowledge relevant to health needs of children. For clinical evaluation of a new drug the study in children should always be carried out after the phase III clinical trials in adults.

☐ For studies prior to phase III the drug has a therapeutic value in a primary disease of the children.

☐ The settings of the research provide the child and parent adequate medical and psychological support.

☐ Interventions intended to provide direct diagnostic, therapeutic, or preventive benefit for the individual child participants must be justified in relation to potential risks involved in the study and potential benefits to society.

☐ The risk presented by interventions not intended to benefit the individual child participant is low when compared to the importance of the knowledge that is to be gained.

☐ Interventions that are intended to provide therapeutic benefit are likely to be at least as advantageous to the individual child participant as any available alternative interventions.

☐ A parent or legal guardian of each child has given proxy consent.

☐ The assent of the child should be obtained to the extent of the child's capabilities such as in the case of mature minors or adolescents, unless there is no medically acceptable alternative to the therapy provided or tested, and consent has been obtained from at least one parent or guardian.

☐ If research involves adults unable to consent, the ethics committee must consider additional safeguards to protect their rights and welfare: When conducting non-therapeutic research, consent must be obtained directly from the participant, unless:

- The objectives of the clinical trial cannot be met by means of a trial in participants who can give consent personally.
- The foreseeable risks to the participants are low.
- The negative impact on the participant's wellbeing is minimized and low.
- The clinical trial is not prohibited by law.
- The opinion of the ethics committee is expressly sought on the inclusion of such participants, and the written opinion covers this aspect.

- Such trials, unless an exception is justified, should be conducted in patients having a disease or condition for which the investigational product is intended. Participants in these trials should be particularly closely monitored and should be withdrawn if they appear to be unduly distressed.

When adults are unable to consent, the EC determines:

☐ A non-therapeutic clinical trial (i.e. a trial in which there is no anticipated direct clinical benefit to the participant) should be conducted in participants who personally give consent and who sign and date the written consent document.

☐ Non-therapeutic clinical trials may be conducted in participants with consent of a legally acceptable representative provided the following conditions are fulfilled:

 The objectives of the clinical trial cannot be met by means of a trial in participants who can give consent personally.

 The foreseeable risks to the participants are low.

 The negative impact on the participant's wellbeing is minimized and low.

 The clinical trial is not prohibited by law.

 The opinion of the EC is expressly sought on the inclusion of such participants, and the written opinion covers this aspect.

 Such trials, unless an exception is justified, should be conducted in patients having a disease or condition for which the investigational product is intended. Participants in these trials should be particularly closely monitored and should be withdrawn if they appear to be unduly distressed.

Pregnant or nursing women:

Pregnant or nursing women should in no circumstances be the participant of any research unless the research carries no more than minimal risk to the fetus or nursing infant and the object of the research is to obtain new knowledge about the fetus, pregnancy and lactation. As a general rule, pregnant or nursing women should not be participants of any clinical trial except such trials as are designed to protect or advance the health of pregnant or nursing women or fetuses or nursing infants, and for which women who are not pregnant or nursing would not be suitable participants.

a. The justification for participation of these women in clinical trials would be that they should not be deprived arbitrarily of the opportunity to benefit from investigations, drugs, vaccines or other agents that promise therapeutic or preventive benefits. Example of such trials are, to test the efficacy and safety of a drug for reducing perinatal transmission of HIV infection from mother to child, trials for detecting fetal abnormalities and for conditions associated with or the sake of participation in research and in case she decides to do so, harm of cessation of breast-feeding to the nursing child should be properly assessed except in those studies where breast feeding is harmful to the infant. Compensation in terms of supplying supplementary food such as milk formula should be considered in such instances.

b. Research related to termination of pregnancy: Pregnant women who desire to undergo Medical Termination of Pregnancy (MTP) could be made participants for such research as per The Medical Termination of Pregnancy Act, GOI, 1971.

c. Research related to pre-natal diagnostic techniques: In pregnant women such research should be limited to detect the foetal abnormalities or genetic disorders as per the Prenatal

Diagnostic Techniques (Regulation and Prevention of Misuse) Act, GOI, 1994 and not for sex determination of the foetus.

Vulnerable population will be subjected to full board Initial review. Research involving vulnerable populations is not eligible for expedited review or exemption from review.

- The EC evaluates whether additional safeguards have been included in the study to protect the rights and welfare of vulnerable participants.
- The EC requires at least one or more individuals who are knowledgeable about or have experience in working with these participants are part of the review process.
- New study submissions, amendment and continuing review applications involving vulnerable populations (except prisoners, which should be reviewed by the full board) may be reviewed by the convened board or by expedited review,as decided during initial review and as per SOP.
- The research protocol involving Vulnerable population will be reviewed according to current requirement and guidelines. The decisions are arrived at using the approved checklist for reviewers.
- If the research includes a vulnerable population that is not covered in the above list or there are no national or international guidelines for ensuring protections. EC will evaluate the research proposal to ensure that precautions are taken to protect the participants.

The protocol should be reviewed keeping in mind the following points:

 Measures to protect autonomy,

 Risk/benefit determinations with respect to the vulnerability

 Whether vulnerable subjects are bearing unequal burden in research.

Members of the EC who would be reviewing such protocols should be well versed with the potential harm or risk of such population participating in the study. The checklist for different vulnerable populations should be used. Special justification is required for inviting vulnerable individuals to serve as research subjects and, if they are selected, the means of protecting their rights and welfare must be strictly adhered to.

The extent of protection afforded should depend upon the risk of harm and the likelihood of benefit. The judgment that any individual lacks autonomy should be periodically reevaluated and will vary in different situations. The central issue for the EC to consider is whether the potential subject's ability to exercise free choice is limited in some way.

Reviewing research protocol involving vulnerable population:

When researchers are likely to approach subjects who lack the ability to consent, the EC evaluates whether:

☐ The proposed plan for the assessment of the capacity to consent is adequate.

☐ Assent/surrogate consent of the participants is a requirement wherever possible,

and, if so, whether the plan for assent/ surrogate consent is adequate.

☐ There is adequate room for ensuring the involvement of the LAR in the

consenting process

☐ When a research participant regains consciousness from unconscious state or

is mentally competent to understand the study. If such an event is expected then procedures to address it should be spelt out in the informed consent form.

The EC Secretariat is responsible for receiving, verifying, and managing the hard copies of the received research protocols pertaining to vulnerable groups based on new and evolving applicable regulations and guidelines as per the checklist.

The Secretariat should create a study specific file, distribute the packages and study assessment forms to the EC members for review with the updated checklist, and communicate the review results to the investigators.

 It is the responsibility of the EC Secretariat to maintain up-to-date tools (e.g. checklist) for review of research pertaining to vulnerable groups based on new and evolving applicable national and international regulations and guidelines.

 Maintain file for update-checklist (1-5) which conforms to recent / current applicable regulations and guidelines.

The Member Secretary will assign two or more members of the EC who have a thorough understanding of the ethical review process and experience in the field of research to review such type of protocols. The reviewers should be familiar and trained in the concept of vulnerability and protections for participants with diminished autonomy.

EC Chairperson/ Member Secretary is responsible for ensuring that EC members are well versed in new and evolving regulations and guidelines pertaining to vulnerable populations through regular training programs, for selecting primary reviewers with appropriate expertise

to conduct the reviews of such research, and for securing appropriate consulting expertise as needed for selected reviews.

EC members are responsible for receiving, verifying, and reviewing the research protocols pertaining to vulnerable populations using study assessment form and checklist.

EC is responsible for conducting appropriate review of research planned for vulnerable populations, including an assessment of potential for coercion, in consultation with any appropriate experts and resources as described in this SOP.

EC Members will review the protocol and the informed consent document or assent form.

The suggestions that are agreed upon by the EC members present at the meeting will be discussed.

RISK DETERMINATION	**BENEFIT ASSESSMENT**	**EC ACTION**
Minimal	With or without direct benefit	Approvable
Greater than minimal risk	Potential benefit	Approvable
Greater than minimal risk	No direct benefit to individual but offer general knowledge about the condition or disorder and may benefit to the society or future generations are likely to benefit	Approvable case-by-case with special safeguards

7.3 DECISION MAKING

A member will be asked to withdraw from the meeting for the decision procedure concerning an application where there arises a conflict of interest; the conflict of interest should be indicated to the chairperson prior to the review of the application and recorded in the minutes. Decisions will only be made at meetings where a quorum is present. Only members who participate in the review will participate in the decision-making. Decisions may be arrived at consensus, where possible; when a consensus appears unlikely, the EC will vote. In cases of conditional decisions, clear suggestions for revision and the procedure for having the application re-reviewed will be specified. A negative decision on an application will be supported by clearly stated reasons. The decision will be communicated in writing to the applicant according to EC procedures, preferably within two weeks after the meeting at which the decision was made. EC should receive notification from the applicant at the time of the completion of a study.

The investigators will be asked to provide a follow-up and progress of the trial under the following situations:

- Any protocol amendment likely to affect the rights, safety, and/or well-being of the research participants or the conduct of the study
- Serious and unexpected adverse events related to the conduct of the study or study product, and the response taken by investigators, sponsors, and regulatory agencies
- Any event or new information that may affect the benefit/ risk ratio of the study

The Committee will give its opinion on the projects in one of the following ways:

- **Approval.**
- **Disapproval.**
- **Modification before Approval - (Conditional Approval).**
- **Discontinuation of previously Approved project**.

7.4 REVIEW OF PROGRESS OF STUDY

 All the approved studies will be reviewed Annually. The EC is responsible for determining the date of continuing review if the project will be renewed more frequently in the year. This decision is taken during the EC meeting wherein the project is finally approved.

 EC is primarily responsible for renewing the study progress, the occurrence of unexpected events or problems, and the rate of accrual of participants. The protocol, informed consent documents and assent documents are examined to ensure that the information remains accurate.

 The EC has the same procedure for decision making on a continuing review application as for an initial review application. All the steps followed for initial review detailed in earlier

sections will therefore be applicable. The decision is made as approval to continue the study; revision or disapproval.

 It is the responsibility of the EC Secretariat to send reminders to PIs regarding the submission of Continuing Review Application/Annual Status Report.

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7.5 ON-SITE VERIFICATION

Decisions on on-site verification of studies will be taken on a case-by case basis by a full meeting of the EC.

Before the visit, The EC representatives will

 Contact the site to notify them that they will be visiting them. At that time, the monitor and the site will coordinate a time for the site evaluation visit

 Make the appropriate travel arrangements.

 Review theEC files for the study and site,

 Make appropriate notes, or Copy some parts of the files for comparison with the site files.

During the visit, The EC representatives will

 Review the ICD to make sure that the site is using the most recent version

 Review randomly the participant files to ensure that participants are signing the correct informed consent

 Observe the informed consent process, if possible

 Observe laboratory and other facilities necessary for the study at the site

- Review theEC files for the study to ensure that documentation is filed appropriately
- Collect views of the study participants.
- Debrief the visit report/comments
- Get immediate feed back.

After the visit, he EC representative will:

- Write a report/comment within 2 weeks describing the findings during the audit
- Forward a copy of the site visit to the 'site monitoring' file for Full Board review.
- Send a copy of the report to the site for their files, and
- Place the report in the correct site files.
- Present the inspection results to the Full Board
- Consult with theEC secretariat
- Schedule the presentation in the meeting agenda.
- Present the results of on-site inspections to the Full Board.
- Notify the investigator
- Keep records and follow up

NON-COMPLIANCE PROCEDURES:

Whenever protocol deviation / non-compliance / violation has been observed:

- Ensure that the issues as well as the details of non-compliance involving research investigators are included in the agenda of the EC meeting.
- Maintain a file that identifies investigators who are found to be non-compliant with national / international regulations or who fail to follow protocol approval stipulations or fail to respond to the EC's request for information/action.

 The Board may elect to suspend or terminate approval of current studies or refuse subsequent applications from the investigators cited. Such decisions are recorded in the minutes.

7.6 REVIEW AND FOLLOW-UP OF SERIOUS ADVERSE EXPERIENCES (SAE)

 The primary responsibility of the EC is to review and address SAE and unexpected events involving risks to subjects or others as well as ethic; complaints. In addition, the Committee is authorized to offer mediation under appropriate circumstances.

 EC should also make sure that researchers are made aware of the policies and procedures concerning reporting and continuing review requirements.

 The EC Secretariat is responsible for first screening the assessment of the reports and seeing whether they need a review of full Board. Chairperson, other qualified EC members or experts. EC should also make sure that researchers are made aware of the policies and procedures concerning reporting and continuing review requirements.

 The EC Secretariat is responsible for first screening the assessment of the reports and seeing whether they need a review of full Board. Chairperson, other qualified EC members or experts.

 The PI / designated person should directly inform the report of any SAE to the EC Chairperson according to the timelines given in the Government of India (Ministry of Health and Family Welfare. Department of Health) notification on "Compensation in case of injury or death during clinical trial" dated 30 January 2013.

COMPENSATION FOR INJURY OR DEATH DURING THE TRIAL:

 INJURY

- Free medical management of present and subsequent clinical outcomes for as long as required
- If injury is related to the trial, financial compensation as mandated by relevant authorities. The compensation shall be over and above the medical expenses incurred in the management.

 DEATH

- Financial compensation to the nominee(s) of the subject; including for unborn children.
- An independent expert committee shall hold an enquiry as to the circumstances of the death and recommend the quantum of compensation.
- The sponsors and/or their representatives who obtained permission to conduct the study shall be responsible for compensation if the adverse event was due to faulty product or procedures recommended by them.
- Violation of protocol, scientific misconduct or negligence of any of the stakeholders will also be dealt with and appropriate civil/criminal proceedings may be initiated.

 PROCEDURE FOR ADVERSE EVENT REPORT:-

- The Principal investigator is required to prepare and submit a detailed report on the adverse event to the Chairman, Ethics committee, within 10 calendar days of the occurrence, with copies to the Licensing Authority, Expert committee, and Head of the Institution.

- The Ethics committee shall prepare and submit a report along with its recommendations, to the Expert committee and the Licensing Authority within 21 calendar days of the occurrence of the adverse event.
- The expert committee shall examine the report of serious adverse event of death and give its recommendations to the licensing authority for the purpose of arriving at the cause of the adverse event within thirty days of receiving the report from the Ethics committee, and the expert committee while examining the event, may take into consideration, the reports of the investigator, sponsor or his representative whosoever had obtained permission from the licensing authority for conducting the clinical trial and the Ethics committee.
- The expert committee recommendations will be examined by the Licensing authority and appropriate orders shall be passed within three months after receiving the report.
- (The principal rules were published in the Gazette of India vide notification No.F.28-10/45-H (1) dated the 21st December 1945 and last amended vide notification number G.S.R. 844(E). dated the 26th November 2012.)

PROTECTION OF PARTICIPANTS RIGHTS:

 TheEC considers protection of the rights and welfare of the human subjects participating in a clinical research approved by the EC as its primary responsibility.

 Informed Consent documents reviewed by the EC inform the study participant that query regarding their rights as a participant in the study may be addressed to the EC Member secretary, and the EC address and phone number are provided.

 This provides guidelines for dealing with and accommodating requests by participants/patients regarding their rights as a participant or to resolve their complaints in any approved research study.

 This is applicable to all requests concerning the rights and well being of the research participants participating in studies approved by the EC

 It is the responsibility of the EC Member Secretary to provide the required information to the research participants/ research participant s representatives, in the case of queries received.

 It is the responsibility of the Member Secretary/Chairperson to initiate a process of giving information to the participants or identifying and addressing any injustice that has occurred if complaints are received from research participants.

 Any queries shall be raised at the next meeting of the Ethics committee or any subcommittee constituted for the purpose.

 The proceedings regarding the participant queries shall be forwarded to the Principal Investigator and a discussion will ensue to reach a final decision after taking into account the views of all stakeholders.

 The final decision will be intimated in writing to the study participant.

7.7 PREMATURE TERMINATION / SUSPENSION / DISCONTINUATION OF A STUDY

The EC has determined procedures for termination, suspension or discontinuation of a study based on recommendations of the PI, the committee itself, and of stakeholders like sponsors, other authorized bodies. This applies to studies previously granted approval.

The secretariat will receive recommendation and comments from PI, Sponsor or other authorized bodies for premature termination of study.

 The EC members / Chairperson can prematurely terminate the study if protocol noncompliance / violation is detected and EC decision is to terminate the study due to any reason.

For e.g.- Frequency of SAEs, occurring at trial site may require the study to be prematurely terminated for the safety of the patients.

 The secretariat will inform the PI to prepare and submit a protocol termination package along with Premature Termination Report (available at EC office)

 The secretariat will receive the study protocol termination prepared and submitted by the PI and verify the contents of the report for inclusion of:

Premature Termination Report / suspension / discontinuation signed and dated by the PI and/or other material (letter from Principal Investigator / sponsor etc.)

- The Secretariat will check the completeness of the information
- The Secretariat will receive and acknowledge the reports.
- Review and discuss the Termination / suspension/discontinuation report
- EC will review the termination report suspension/discontinuation at regular full board meeting or expedited review meeting.
- The Secretary in the meeting will inform of the premature termination suspension / discontinuation of the project and the EC members will review the Premature Termination Report along with relevant SAE reports
- If the Premature Termination Report suspension / discontinuation is, unclear, more information is required from the PI. The Secretariat is instructed to send a query to the PI.
- The Secretariat will prepare a notification letter acknowledging the acceptance of termination / suspension / discontinuation or query letter to request information regarding the premature termination / suspension / discontinuation.
- The Secretariat will send the notification letter to the PI for their records within 14 days after the meeting. If a query is sent to PL on receipt of the reply letter, it is reviewed in the forthcoming full board meeting / expedited review meeting.
- The secretariat will keep the original version of the Premature Termination suspension / discontinuation report in the study file and send the file to archive. The study documents will be stored for a period of 5 years or more from the date of project termination.

7.8 REVIEW OF COMPLETION OF STUDY

This applies to the review of the Study Completion Report, which is a mandatory review of each investigator's activities presented to the EC as a written report of study completed. Although EC provides a Study Completion Report Form to the investigator, additional information (letter format, form provided by the Sponsor, etc.) maybe submitted to provide adequate and sufficient information. It is the responsibility of the EC members to review the study- completion report and notify- it or request for further information, if necessary.

Detailed instructions before each board meeting:

- TheEC Secretariat will receive 12 hard copies of Study Completion Reports from the PI.

- The Secretariat will follow the guidelines given in the Management of Research study Submission for receiving and checking the report documents.

- The EC Secretariat will review the report for completeness before submission to the EC Members.

- The Member Secretary should keep the study completion reports on the agenda for EC meeting.

Before and during EC meeting:

 EC member(s) will review a copy of the completion report.

 The PI will present the report to the Committee.

 The members will discuss the report in theEC meeting.

 If appropriate to the discussions, the chairperson may call for consensus to accept it or request further information or take any other action.

After the EC meeting:

 The secretariat will note the decision in the meeting minutes and the study will be considered as closed if the document is accepted.

 TheEC decision is communicated to the investigator In case, further information action is requested; the same should be followed by the PI and communicated to the EC office within 30 days. This update will be tabled m the full board meeting of EC.

 Once the report is accepted byEC, the Secretariat will file the report in the study master file.

 TheEC secretariat will archive the entire study as per the instructions given in the SOP and the report for a period of 5 years or more (as mentioned in the protocol) from the date of completion of the project, if the report is accepted.

8 DOCUMENTATION AND ARCHIVING

8.1 EC RECORDS

EC records will include the following:

- EC members' records
- Appointment and Acceptance letters of each member
- Updated Curriculum vitae
- Training records for eachEC member
- Documentation of resignations, terminations
- Confidentiality undertaking form from eachEC Member
- Conflict of Interest declaration form signed and dated by eachEC Member
- EC membership roster
- EC attendance roster
- EC meeting agenda and minutes
- Standard Operating Procedures
- National and International guidelines
- Protocol files with complete history

- Any other correspondence

- Access toEC records

EC records will be made available for inspection to authorized representatives or regulatory authorities after receiving the request in writing.

8.2 AGENDA PREPARATION, PROCEDURES AND RECORDING OF MINUTES

1. The EC Secretariat prepares the agenda two weeks before the actual proposed meeting and circulates to all the EC Members and Investigators in the institution and files the same in the meeting folder.

2. The proposals for presentation, review and discussion are listed on a first come first serve basis.

3. The meeting arrangements are being supervised by the Secretariat with the help of administration and it is the responsibility of the Secretariat to ensure that all the necessary equipment is kept in good housekeeping condition.

4. The meeting will always be held at the Board Room adjacent to the Principal office. If there is any modification in the venue, the same will be intimated to the members and concerned investigators well in advance to prevent inconvenience.

5. On the day of meeting, the Chairperson will be requested to conduct the meeting. The Chairperson with the help of the Member Secretary will ensure the quorum required for reviewing the proposals listed in the agenda.

6. The Chairperson will request the Members and Investigators who attend the meeting, whether they have any conflict of interest involved in the proposals listed for review. If any Member or Investigator declares any conflict of interest, the same will be recorded in the minutes and the declared person will not attend the presentation, discussion and decision making process of the particular proposal.

7. The Chairperson will request the concerned Investigators to present the proposals as per the order listed in the agenda and the same will be taken up for discussion. The comments and discussion points will be recorded in the minutes.

8. The decision making process will be done after the presentation and discussion of each proposal. The same will be arrived at consensus and not by voting. If any Member/s has any difference of opinion, the same has to be clarified in the meeting.

9. If any person has COI, the Chairperson will ensure that all persons with COI do not attend the decision-making.

10. If the Investigator is requested by the EC to submit addition documents/evidence, the Investigator will submit the same within a specified time to the Secretariat. The documents will be circulated to the EC and the decision will be arrived. Till then, the decision is given as "Revision requested".

11. It is the responsibility of the Member Secretary to prepare the minutes and obtain the approval from the Chairperson after getting comments from all the EC Members. The same will be done within 2 weeks of after preparation of the draft minutes.

12. The Member Secretary in the standard formats given in concerned SOPs will prepare the decision letters. The same will be issued to the Investigators after obtaining acknowledgement for receipt.

13. Issuing the decision letters to the PIs will complete the Meeting procedure.

8.3 PROCEDURE FOR MAINTAINING INCOME AND EXPENDITURE

The accounts office will maintain the statement of Income and expenditure; a copy will be in possession of the Member Secretary.

9 NOTIFICATIONS & AMENDMENTS

This SOP is to be reviewed regularly and amended as and when required by the EC in a procedure devised by the Chairperson as appropriate.

ANNEXURES

ANNEXURE 1

Institute Ethics Committee
SRI VENKATESWARA DENTAL COLLEGE &HOSPITAL, CHENNAI
Request for new / Change in SOP

SOP	
Title:	
Details of problems or deficiency in the SOP:	
Identified by: (name of the person designation)	Date (DD/MM/YYYY):
The sections given below are to be filled by the Secretariat	
Discussed in IEC meeting held on:	
Formulation of new SOP / revision required: ☐ Yes ☐ No	
If yes, to be carried out by whom?	
If no why not? Whether the decision communicated to the requester? ☐Yes ☐No Date of communication	
Date SOP finalized:	
Date SOP approved:	
Date SOP becomes effective:	

ANNEXURE 2

Institute Ethics Committee
SRI VENKATESWARA DENTAL COLLEGE &HOSPITAL, CHENNAI
Member Consent

From

To

The Principal
Sri Venkateswara Dental College & Hospital
Thalambur
Chennai -600130

Sub: Consent to be a member of Institute Ethics Committee – Reg

Ref: Your letter No. dated:

Dear Sir:,

In response to your letter stated above, I consent to be a member of IEC of Sri Venkateswara Dental College & Hospital.

I shall maintain the entire research project related information confidential and shall not reveal the same to anyone other than the investigators.

I herewith enclose my CV.

Thanking you,

Yours Sincerely

Signature

Name

Address:

Telephone No.

E Mail.

ANNEXURE 3

Institute Ethics Committee
SRI VENKATESWARA DENTAL COLLEGE &HOSPITAL, CHENNAI
Confidentiality Undertaking Form For IEC Members

In recognition of the fact that I. Dr/Mr/Ms.
Herein referred to as the "Undersigned", have been appointed as a member of the IEC
And would be requested to assess research studies involving human participants in order
To ensure that they are conducted in a humane, scientific and ethical manner, with the
Highest standards of care according to the applied national, local regulations,
Institutional policies and guideline, sign the following undertaking in the capacity of
Member / Chairperson of IEC - SVDCH

Whereas, the appointment of the undersigned as a member of the IEC is based on
Individual merits and not as an advocate or representative of a home province/ territory/ community nor as the delegate of any organization or private interest:
Whereas, the fundamental duty of an IEC member is to independently review research protocols involving human subjects and make a determination and the best possible objective recommendations, based on the merits of the submissions under review;

Whereas, the IEC must meet the highest ethical standards in order to merit the trust and confidence of the communities with respect to the protection of the rights and well being of human subjects:

The undersigned, as a member of the IEC is expected to meet the same high standards of ethical behavior to carry out its mandate.

This Agreement thus encompasses any information deemed Confidential or Proprietary provided to the Undersigned in conjunction with the duties as a member of the IEC. Any written information provided to the Undersigned that is of a Confidential. Proprietary, or Privileged nature shall be indentified accordingly.

As such, the undersigned agrees to hold all Confidential or Proprietary trade secrets (“information”) in trust or confidence and agrees that it shall be used only for contemplated purposes, shall not be used for any other purpose or disclosed to any third party. Written Confidential information provided for review shall not be copied or retained. All Confidential information (and any copies and notes thereof) shall remain the sole property" of the IEC and shall be returned to the IEC secretariat after review.

The Undersigned agrees not be disclose or utilize, directly or indirectly, any Confidential or Proprietary information belonging to a third party" in fulfilling this agreement. Furthermore, the Undersigned confirms that his /his performance of this agreement is consistent with SRI VENKATESWARA DENTAL COLLEGE & HOSPITAL policies and any contractual obligations it may have to third parties.

Undersigned Signature Date:

ANNEXURE 4

Institute Ethics Committee

SRI VENKATESWARA DENTAL COLLEGE &HOSPITAL, CHENNAI

Conflict of Interest

It has been recognized that the potential for conflict of interest will always exist but faith and confidence are vested in the IEC and its Chairperson to manage the issues of conflict so that the ultimate outcome of protection of human subjects is achieved.

In accordance of the policy of the IEC, he / she shall not participate in the review, comment or approval of any activity in which he / she have a conflict of interest, except to provide information as requested by the IEC. The Undersigned will immediately disclose to the Chairperson of the IEC any actual or potential conflict of interest that he / she may have in relation to any particular proposal submitted for review by the committee, and to abstain for any participation in discussions or recommendations in respect of such proposals.

If an applicant submitting a protocol believes that an IEC member has a potential conflict, the investigator may request that the member be excluded from the review of the protocol. The request must be in writing and addressed to the Chairperson. The request must contain evidence that substantiates the claim that a conflict exists with the IEC member(s) in question. The IEC may elect to investigate the applicant's claim of the potential conflict.

Examples of conflict of Interest cases may be any of the following:

A member is involved in a potentially competing research program. Access to funding or intellectual information may provide an unfair competitive advantage. A member's personal biases ma interfere with his or her impartial judgment.

Agreement on Confidentiality and Conflict of Interest

In the course of my activities as a member of the IEC. I may be provided with confidential information and documentation (which we will refer to as the "Confidential Information"). I agree to take reasonable measures to protect the Confidential information: subject to applicable legislation, including the access to it as per the right to information Act not to disclose the Confidential Information to any person: not to use the Confidential Information for any purpose outside the IECs mandate, and in particular, in a manner which would **result** in a benefit to myself or any third party: and to return all Confidential Information (including any minutes or notes I have made as part of my Committee duties) to the Chairperson upon termination of my functions as a Committee member.

Undersigned Signature

Date

Whenever I have a conflict of interest. I shall immediately inform the committee not to count me toward a quorum for consensus or voting

I. Dr./Mr/Ms._.....have read and I Accept the aforementioned terms and conditions as explained in this Agreement

Undersigned Signature

Date

ANNEXURE 5

Institute Ethics Committee
SRI VENKATESWARA DENTAL COLLEGE &HOSPITAL, CHENNAI

Confidentiality Agreement Form for Independent Consultants

I..... (Name and Designation) as a non- member of IEC understand that the copy(ies) given to me by the IEC is (are) confidential. I shall use the information only for the indicated purpose as described by the IEC and shall not duplicate, give or distribute these documents to any person(s) without permission form the IEC.

Upon signing this form. I agree to take reasonable measures and full responsibility to keep the information as confidential.

Undersigned Signature
Date

Chairperson of IEC
Date

I,_____(Enter name) acknowledge that I have received a copy of this Agreement signed by Chairperson. IEC and me

Signature of the recipient
Date

ANNEXURE 6

Institute Ethics Committee
SRI VENKATESWARA DENTAL COLLEGE &HOSPITAL, CHENNAI

Confidentiality Agreement Form for Observer Attendees

I, _____ understand that I am allowed to observe IEC activities and attend the IEC meeting / scheduled on ……at… am/pm as an Observer.

I understand that the course of the observer-ship / meeting of the IEC some confidential information may be disclosed or discussed.

Upon signing this form. I ensure that to take reasonable measures to keep the information and discussion as confidential and ensure confidential documents will be returned to the Secretariat after completion of the review and IEC meeting.

Signature of the Observer Date

Member Secretary" / Chairperson of IEC Date

I. _____(Enter name) acknowledge that I have received copy of this Agreement signed by Member Secretary / Chairperson, IEC and me.

Undersigned Signature Date

ANNEXURE 7

Institute Ethics Committee
SRI VENKATESWARA DENTAL COLLEGE &HOSPITAL, CHENNAI

Form to be filled by the Principal Investigator (PI) for submission to Institute Ethics Committee (IEC)
(For attachment to each copy of the proposal)

Code No. of IEC:*

*To be filled by IEC Secretariat

Proposal Title:

_____

_____

_____

_____

	Name, Designation & Qualifications	Department Tel Nos. Email ID	Signature
PI			
Co-PI/ Collaborators 1.			
2.			
3.			

Please attach Curriculum Vitae of all Investigators. The investigators should sign their CV

ANNEXURE 8

Institute Ethics Committee
SRI VENKATESWARA DENTAL COLLEGE &HOSPITAL, CHENNAI

Undertaking by the Principal Investigator

1. NAME AND OCDE NUMBER OF THE PROJECT

2. NAME, DESIGNATION AND DEPARTMENT OF THE PRINCIPAL

3. OTHER MEMBERS OF THE RESEARCH TEAM

4. NAME AND ADDRESS OF ANY OTHER MEDICAL COLLEGE, HOSPITAL OR INSTITUTION WHERE PARTS OF THE STUDY WILL BE DONE

5. NUMBERS OF ONGOING PROJECTS / CLINICAL TRIALS IN THAT YOU ARE PI

1. I confirm that I will initiate the study only after obtaining all regulatory clearances.
2. I will not implement any deviation from the approved protocol without prior consent of
The sponsor nature and it will be intimated to the IEC at the earliest.
3.I confirm that the CO PI and other members of the study team have been informed about theirobligations and are qualified to meet them
4. I will personally supervise the study and ensure that requirements of obtaining informed consentand other ethical requirements under ICMR and National Regulatory Guidelines are adhered to.
5. I will maintain accurate and complete record of all cases and make them available for audit/ inspection by IEC, Regulatory authorities, Sponsors or theirauthorized representatives.
6. I will inform the IEC and the Sponsors of any unexpected or serious adverse event at the earliestand definitely within seven days of its occurrence.
7. I will maintain confidentiality of the identity of all participating subjects and assure guidelines applicable to such clinical studies.
8. I and my colleagues will comply with statutory obligations, requirements and guidelines applicableto such clinical studies.
9. I will inform IEC of the date of starting the study within 2 weeks of initiation of the trial and submit annual progress reports and final report to Member Secretary, IEC within 4 weeks of the due date.

Signature of Principal Investigator Date

ANNEXURE 9

Institute Ethics Committee

SRI VENKATESWARA DENTAL COLLEGE &HOSPITAL, CHENNAI

One Page CV

Last Name	First Name	Middle/initial
Date of Birth (dd/mm/yy):		Gender
Study Site Affiliation (e.g Principal Investigator, Co-Investigator, (Coordinator)		
Professional Mailing Address (include institution name)	Study Site Address (include institution name)	
Telephone (Office)	Mobile Number:/E-Mail:	
Academic Qualifications (Most current qualification first)		
Degree/ Certificate Year		Institution, Country
Current and Previous 3 Relevant Positions Including Academic Appointments (Most current position first)		
Month and Year Title/Institution/Company,Country		
Brief Summary of Relevant Clinical Reasearch Experience:		
Signature: (Signature Required)	Date:	

ANNEXURE 10

Institute Ethics Committee
SRI VENKATESWARA DENTAL COLLEGE &HOSPITAL, CHENNAI

Contents of a Submitted Package

Protocol Number…….

Initial Review Submitted Package

Cover letter for submission
Project proposal
Curriculum vitae
Protocol Summary Sheet
Proforma for the Investigators
Copy of advertisements (if any)
CPCSEA clearance, if any
Reviewers' form
Protocol and Protocol-Related Documents

Information for subject's	□ informed consent form
Case report forms (CRF)	□study budget
Investigator's brochure	□Data collection tools

Protocol Amendment Submitted Package

Request for Amendment review
Original Amendment Submission Form
Protocol and Protocol-Related Documents

Note: Changes made to the protocol and protocol-related documents should be clearly marked either with the underlining or highlighting feature of the software package used to prepare the document.

Annual Continuing Review Package

Request for Annual Continuing Review
Original Continuing Review Application Form
Current Informed Consent Document (last approved by the IEC)

Protocol Termination Package

Request for reviewing study termination

Original Continuing Review Application Form (Termination Submissions are contained on this form

Protocol Completion report Package

Request for reviewing study termination
Study Completion Report Form
Other relevant document like publications

ANNEXURE 11

Institute Ethics Committee
SRI VENKATESWARA DENTAL COLLEGE &HOSPITAL, CHENNAI
Document Receipt Form

Protocol Number:		**Submitted date:**	

Type of Submission	1.initial Review 2.Protocol Amendments 3.Expedited review 4.Exemption form review	1.Continuing Review of Approved Protocols 2.Protocol Termination 3.Study Completion

Protocol Title:

Principal Investigator:	
Designation:	
Documents submitted:	• Complete • Incomlete,will submit on……..
	Check what documents are received later on.
Documents to be Submitted later:	• Information for subjects • Informed consent form • Case report forms (CRF) • Study budget • Investigator‟s brochure • Others …….
Received by:	
Date received:	

Note: Please bring this with you when contacting the IEC

ANNEXURE 12

Institute Ethics Committee
SRI VENKATESWARA DENTAL COLLEGE &HOSPITAL, CHENNAI
Member Study Review Form

Name of the Member (reviewer): To be written by the IEC Member

***Project ID No:** To be assigned by the IEC Secretariat

Proposal title: To be written by the Investigator

Investigator(s): To be written by the Investigator

* **1. RC Approval** Yes ☐ No ☐

To be written by the Investigator

If yes: Date of approval: DD/MM/YYYY

If No, **state the reason for submitting to the IEC review**

2. Review of scientific content	**Yes**	**No**
a. Is the project original and innovative?	☐	☐
b. Is this an attempt to validate, prove or disapprove the validity of existing knowledge?	☐	☐
c. Does the project have appropriate study design, Work plan and structure to achieve the stated objectives?	☐	☐
d. Does the proposal describe the relevance of the work in The context of contemporary translation or clinical research?	☐	☐
e. The statistical methodology (including sample size calculation)And the potential for reaching sound conclusions with the Smallest number of research participants are appropriately described?	☐	☐
f. Whether appropriate justification for the use of control Arms given in the proposal?	☐	☐
g. Whether the potential of the work that would be conducted To lead into a larger and high impact study has been described?	☐	☐

h. Whether the criteria for prematurely withdrawing research participants, and criteria for suspending or terminating the research as a whole described appropriately? ☐ ☐

i. Whether the provisions made for monitoring and auditing The conduct of the research, including the Constitution of a Data Safety Monitoring Board is adequate? ☐ ☐

j. Whether the investigator"s capability, availability of Infrastructure and scientific environment to conduct thestudy within the time frame, described appropriately? ☐ ☐

k. Whether the policy on study reporting and publication Of the research described? ☐ ☐

3. Risks

i. Individual Yes ☐ No ☐

Ii Societal / Community Yes ☐ No ☐

Ii Is the overall Risk/benefit ratio Acceptable ☐ Unacceptable ☐

4. Benefits

i. Direct ☐ Reasonable ☐ None ☐

ii. Indirect ☐ Improvement in science/knowledge ☐ Any other ☐

5. Subject selection

i. Are Inclusion / exclusion criteria appropriate?

Yes ☐ No ☐

ii. Vulnerable subjects (women, child, mentallychallenged, seriously or terminally ill, fetus, economically or socially backward and healthy volunteers) adequately protected?

Yes ☐ No ☐

iii. Adequate protection for special group of participants, if involved

Yes ☐ No ☐

6. Is description of measures to protect privacy & confidentiality adequate?

Yes ☐ No ☐

7. Participant information sheet Adequate ☐ Inadequate ☐

8. Consent form components addressed Yes ☐ No ☐

Adequately? If not please

Explain _____

9. Compensation, (if applicable) Yes ☐ No ☐

10. Does PI mention any conflict of Yes ☐ No interest? ☐

11. Is any compensation proposed for reimbursement?

Appropriate Inappropriate

If inappropriate, please comment _____

12. 12.

Decision of review	Please tick one
Recommended	☐
Revision	☐
Rejected	☐

Any other remarks / suggestions:

Member's name, signature, & date.

ANNEXURE 13

Institute Ethics Committee
SRI VENKATESWARA DENTAL COLLEGE &HOSPITAL, CHENNAI

Format for communication to the PI by the member secretary

To, Dated:

Prof./Dr. _____

_____

_____

_____

Dear Prof./Dr. _____

The Institute Ethics Committee in its meeting held on _____,has Reviewed and discussed your application to conduct the clinical trial/ project entitled "_____

_____

_____

Sponsored by _____ Code no _____

The following documents were reviewed:

a. Trial Protocol (including protocol amendments)/project, dated _____
b. Investigator‟s Brochure, dated _____
c. Patient Information Sheet and Informed Consent Form (including updates if any) In Tamil, English and /or vernacular language.
d. Proposed methods for patient accrual including advertisement (s) etc. proposed To be used for the purpose.
e. Current CV of investigator.
f. Insurance Policy/ Compensation for participation and for serious adverse events Occurring study participation.
g. Investigator‟s Agreement with the Sponsor.
h. Investigator‟s Undertaking
i. Proforma.
j. Case Report Form
k. Any other/ additional documents

The following members of the ethics committee were present at the meeting held on (date,time, place)

_____ Chairman of the Ethics Committee

_____ Member secretary of the Ethics Committee

_____ Name of each member with designation

We approve the trial to be conducted in its presented form.

The Institutional Ethics Committee expects to be informed about the progress of the Study, any SAE occurring in the course of the study, any changes in the protocol and Patient information / informed consent and asks to be provided a copy of the final report.

Decision of Committee:

Member Secretary Chairman

ANNEXURE 14

Institute Ethics Committee
SRI VENKATESWARA DENTAL COLLEGE &HOSPITAL, CHENNAI

Intimation of start of study

1. Project/ Trial Code Number

2. Title of the drug/ multi centric trial

3. Principal Investigator (Name & Department)

4. Sponsor5.

5. Contract Research Organization (CRO) if any

6. Date of sanction by IEC

7. Date of start

Date: (Signature of Principal Investigator)

ANNEXURE 15

Institute Ethics Committee
SRI VENKATESWARA DENTAL COLLEGE &HOSPITAL, CHENNAI

Expedited Review Application Form

Project ID No.: ——————————— (To be filled by IEC Secretariat)

1. Principal Investigator‟s Name: _____
2. Title of Project: _____
3. Brief description of the project (attach one page summary of the proposal)
4. State reasons why expedited review from IEC is requested? (Tick applicable)

    a. Activity is limited to data analysis or health record research
    b. Anonymous survey/ retrospective chart review:
    c. Analysis of discarded pathological specimens/ stored paraffin blocks without personal identifiers:
    d. Proposal involving previously banked materials and/ or tissues as per policies of respective authorities like – tissue repository:
    e. Research involving clinical materials (data, documents,records, or specimens) That have been collected for non-research (clinical) purposes
    f. Study related documents such as:
        1. Minor deviations from originally approved protocol
        2. Inclusion or deletion of name/s of co-investigator/s
        3. Request for change in PI or hand over of trials or projects
        4. Minor amendments in the protocol.
        5. Minor corrections in budget

    g. Other administrative revisions like change in the name, address of sponsor
    h. Change in contact details of PI and IEC
    i. Are children included in the study?
    j. Does the research involve vulnerable population?
    k. Does the study involve more than minimal risk?
    l. Any other

    Reasons: _____

ANNEXURE 16

Institute Ethics Committee
SRI VENKATESWARA DENTAL COLLEGE &HOSPITAL, CHENNAI

Exemption from IEC Review

Application Form

Project ID No.:——————————————— (To be filled by IEC Secretariat)

1. Principal Investigator's Name: _____
2. Title of Protect: ——————————————————
3. Brief description of the project-Please give a brief summary (approx.300 words) of the nature of the proposal, including the aims /objectives/hypotheses of the project, rationale, participants" description, and procedures/methods to be used in the project.
4. Please check that your application /summary includes:
    - Procedures for voluntary, informed consent
    - Privacy & confidentiality
    - Risk to participants
    - Needs of dependent persons
    - Conflict of interest
    - Permission for access to participants from other institutions or bodies
    - Inducements
5. State reasons why exemptions form IEC review is requested? (Tick applicable)
    a. Audit of educational practices
    b. Research on microbes cultured in the laboratory
    c. Research on immortalized cell lines
    d. Research on cadavers or death certificates which reveals no identifying personal data
    e. Analysis of data freely available in the public domain

f. Any other …….

Principal Investigator‟s

Signature:_____Date _____

Recommendation by the IEC Member Secretary:

Exemption

Cannot be exempted. Reasons _____

Discussion at full board

Signature of the Member Secretary: _____

Date _____

Final Decision:

Exemption

Cannot be exempted.

Reasons _____

_____

Discussion at full board

Signature of the Chairperson: _____ Date _____

Final Decision at Full Board meeting held on _____

Signature of the Chairperson: _____ Date _____

NOTE:

No research can be counted as low risk if it involes:

i. Invasive physical procedures or potential for physical harm
ii. Procedures which might cause mental/ emotional stress or distress, moral orcultural offence
iii. Personal or sensitive issues
iv. Vulnerable groups
v. Cross cultural research
vi. Investigation of illegal behavior (s)I
vii. Invasion of privacy
viii. Collection of information that might be disadvantageous to the participant
ix. Use of information already collected that is not in the public arena which might Be disadvantageous to the participant
x. Use of information already collected which was collected under agreement Of confidentiality
xi. Participants who are unable to give informed consent
xii. Conflict of interest e.g the researcher is also the lecturer, teacher, treatment-provider, Colleague or employer of the research participants, or there is any Other power relationship between the researcher and the research participants.
xiii. Deception
xiv. Audio or usual recording without consent
xv. Withholding benefits from "control" groups
xvi. Inducements

This list is not definitive but is intended to sensitize the researcher to the types of issues to be considered. Low risk research would involve the same risk as might be encountered in normal daily life.

Please check that your application /summary has discussed:

- Procedures for voluntary, informed consent Privacy & confidentiality
- Risk to participants
- Needs of dependent persons
- Conflict of interest
- Permission for access to participants from other institutions or bodies
- Inducements

In some circumstances research, which appears to meet low risk criteria, may need to be renewed

By the IEC. This might be because of requirements of:

- The publisher of the research
- An organization, which is providing funding resources, existing data, access to participants etc.

ANNEXURE 17

Institute Ethics Committee
SRI VENKATESWARA DENTAL COLLEGE &HOSPITAL, CHENNAI

Submission letter format for reviewing the progress of study

To Date:

The Chairperson

Institute Ethics Committee,

SRI VENKATESWARA DENTAL COLLEGE & HOSPITAL.Chennai

Forwarded through the Head of the Department

Dear Sir / Madam.

A study proposal with the details mentioned below is submitted for continuing / annual

Review and discussion during the IEC meeting to be held on dd/mm/yyyy

Project ID:

Protocol Title:

Protocol Version:

Date of Initial approval:

Date (s) of continuing approval (if any)

Principal investigator:

Thanking You.

Signature & Name of the Principal Investigator

Designation.

ANNEXURE 18

Institute Ethics Committee
SRI VENKATESWARA DENTAL COLLEGE &HOSPITAL, CHENNAI

Format of the Progress Report

Date:

1. **Protocol Title:**
2. **Date:**
3. Principal **Investigator:**
4. **Funding Agency-** ICMR / non ICMR; if non ICMR.name of the agency.
5. **Aims /Objective:**
6. **Project status (**tick any one): Implemented / Awaiting funds / Yet to be implemented

   If yet to be implemented: Any preparatory" work has been carried out? If yes. Give details

   In brief
7. **Comments/observations of the committer during the Lat review:**
8. What steps have been initiated to address the comments / observations made by the EC
9. Being implemented in the following study sites:
10. Recruitment:

ANNEXURE 19

Institute Ethics Committee
SRI VENKATESWARA DENTAL COLLEGE &HOSPITAL, CHENNAI

Reminder letter by the IEC Secretariat to the investigator for submission of Progress report

(In IEC Letter Head)

To

Name of Principal Investigator,

Address of Principal Investigator

Ref: Project Title: XXXXXX

Dear Dr./Mr./Ms. Name of Principal Investigator

The above referenced project was approved by the IEC on dd/mm/yyyy and is due for continuing/

Annual review by the IEC

Kindly submit the continuing review application and supporting documents as mentioned

In the SOP before dd/mm/yyyy

Thanking you,

Yours sincerely,

Signature with date

Member Secretary.IEC

ANNEXURE 20

Institute Ethics Committee
SRI VENKATESWARA DENTAL COLLEGE &HOSPITAL, CHENNAI

Premature Termination/Suspension/Discontinuation Report

1. Protocol ID No.:

2. Protocol Tiltle:

3. Principal Investigator:

4. Study Site:

5. Sponsor

6. IEC Approval Date: Date of Last Progress Report Submitted to IEC

7. Study Start Date:

8. Termination/suspension/discontinuation Date:

9. Study Participants

a. Target accrual of trial (entire study) _____

b. Total patients to be recruited (IEC ceiling) _____

c. Screened: _____

d. Screen failures: _____

e. Enrolled: _____

f. Consent Withdrawn: _____ Reason: (Attach in format below)

g. Withdrawn by PI: _____ Reason:(Attach in format below)

h. Active on treatment: _____

i. L Completed treatment: _____

j. Patients on Follow-up: _____

k. Patients lost to follow up: _____

l. Any other: _____

m. Physically _____

UL Cognitively _____

iv. Both _____

10. SAE (Total No.):

11. SAE Event

12. Summary of Results (attach separate sheet):

13. Reason for Termination/Suspension/Discontinuation (Attach separate sheet):

PI Signature Date:

ANNEXURE 21

Institute Ethics Committee
SRI VENKATESWARA DENTAL COLLEGE &HOSPITAL, CHENNAI
Checklist of a Monitoring Visit

Protocol ID	Date of the Visit:
Study Title:	
Principal Investigators:	Phone:
Institute:	Address:
Sponsor.	Address:
Total number of participants:	Total particpants enrolled:
Are site facilities appropriate? ☐ Yes ☐ No	Comment:
Are Informed Consents recent? ☐ Yes ☐ No	Comment:
Any adverse events forund? ☐ Yes ☐ No	Comment:
Any protocol non-compliance /violation? ☐ Yes ☐ No	Comment:
Are all case Record Forms up to date? ☐ Yes ☐ No	Comment:
Are storage of data and investigational products Locked? ☐ Yes ☐ No	Comment:
How well are participants protected? ☐ Good ☐ Fair ☐ Not good	Comment:
Any outstanding tasks or results of visit? ☐ Yes ☐ No	Give details:
Duratiion of visit…….hours Starting from:	Finish:
Name of IEC Members / representatives and Accompanying persons	
Completed by:	Date:

ANNEXURE 22

Institute Ethics Committee
SRI VENKATESWARA DENTAL COLLEGE &HOSPITAL, CHENNAI

Format for the management of investigators who fail to follow or to comply with guidelines

Deviation / Non-Compliance / Violation Record

Protocol ID:	Date…….
Study Title:	
Investigator	Contact No.:
Institution	Contact No.:
Sponsor:	Contact No.:
☐ Deviation from protocol ☐ Non-Compliance ○ Major ☐ Violation	
Description:	
IEC's Decision:	
Actions taken:	Outcome:
Found by:…… Date:……	Reported by:…… Date:……

ANNEXURE 23

Institute Ethics Committee
SRI VENKATESWARA DENTAL COLLEGE &HOSPITAL, CHENNAI

Format for the Reporting of Serious Adverse Experiences

Principal Investigator……. Protocol No.

Report Date…….

Study Title……

Name of the study medicine /device…….....

Sponsor……

☐ Initial ☐ follow-up

Onset date:……

Subject initial /number:	Age Male Female
Subject history:	Laboratory findings:
SAE:	Treatment:Outcome: ☐ Resolved ☐ Ongoing

If the SAE occurred on site, did you report it to the sponsor and / or DCGI? _____

- For on site reports, attach the SAE report you submitted to the sponsor and indicate The following: date of SAE brief description of SAE including outcome, intensity, action Taken, any medical records your might find pertinemt.
- If the SAE occurred off-site, was it reported by an outside agency?
  - ○ For off-site SAEs, attach formal reports filed with the sponsor.
- Is this SAE mentioned as a risk in the consent form?.....
- Was the SAE an expected adverse event of the treatment or device?

An On-Site SAE that occurs during a study should be reported to IEC Immediately.

- Has the on-site SAE been reported to IEC?.....

Seriousness:	Relation to O Drug O Device O study
☐ Death	☐ Not related
☐ Life Threatening	☐ Possibly

☐ Hospitalization- ☐ initial	☐ Probably
☐ prolongation	☐ Definitely related
☐ Disability / Incapacity	☐ Unknown
☐ Congenital Anomaly	
☐ Other……..	

Changes to the protocol recommended?	☐ No ☐ Yes Attach proposal
Changes to the informed consent form Recommended?	☐ No ☐ Yes Attach proposal
Renewed by …….	Date…….
Comment……	Action……

ANNEXURE 24

Institute Ethics Committee
SRI VENKATESWARA DENTAL COLLEGE &HOSPITAL, CHENNAI

Participant Request Record Form

1. Date Received:

2. Received by:

3. Request from:

- Telephone calls No……..
- Fax No……..
- Letter / Date…….
- E-mail /Date…….
- Walk-in /Date / Time……..
- Other, specify……

4. Participant‟s Name:

5. Contact Address:

6. Phone:

7. Title of the Study:

8. Protocol ID No:

9. Starting date of participation:

10. Request:

11. Action taken

12. Outcome:

Signature of the Chairperson

……Date……

Signature of the Member

Secretary…… Date……..

ANNEXURE 25

Institute Ethics Committee
SRI VENKATESWARA DENTAL COLLEGE &HOSPITAL, CHENNAI

Format for review of completion of study

Study Start Date

Completion Date

Summary of Protocol participants:

Sample size (entire study)_____

Total patients to be recruited at each site_____

a. Screened _____
b. Screen failures _____
c. Enrolled:_____
d. Consent Withdrawn:_____Reason:
e. Withdrawn by PI_____Reason:
f. Active on treatment _____
g. Completed treatment:_____
h. Patients on Follow-up _____
i. Patients lost to follow up:_____
j. Any other:_____

Any Impaired participants

a. None_____
b. Physical_____
c. Cognitive_____
d. Both_____

Results (brief) (use extra blank sheets, if more space is required)

SAEs observed (Total number and type)

a. Whether all SAEs were intimated to the IEC (Yes No)

Protocol deviations violations (Number and nature)

Conclusion

Presentation publication related to the data generated in this study

Signature of PI

ANNEXURE 26

Institute Ethics Committee
SRI VENKATESWARA DENTAL COLLEGE &HOSPITAL, CHENNAI
Informed Assent Form

Study Tide

Participant ID No:

"I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this study and understand that I can say NO to taking part in the study, even if my parents have agreed to my participation. I understand I have the right to withdraw from the study at any time without giving any reason, without anyone upset at me. or my medical care or legal rights being affected. _____

_____

Date | Name of the child participant | Signature/thumb impression of the child participant

[The literate selected by the participant must sign the informed consent form. The witness should not have any relationship with the research team. If the participant doesn't want to disclose his / her participation details to others, in no* of respecting the wishes of the participant he / she can be allowed to waive from the witness procedure (This is applicable to literate participant ONLY). The study staff should document this by getting signature from the prospective participant]

"I have witnessed the accurate reading of the consent form to the potential participant and the individual has had opportunity to ask questions. I confirm that the individual has given consent freely"

_____ _____

Date | Name of the witness | Signature of the witness

_____ _____

Date | Name of theInterviewer | Signature of the interviewer

Parent/guardian has signed an informed consent: Yes_____No_____

Initialed by the researcher